

REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

Claims 1 - 10, 13 - 19 and 21 - 45 are pending.

Claim 26 is amended.

Claims 1 - 10, 13 - 19 and 21 - 45 were rejected.

Rejections under 35 U.S.C. §103

2. and 3. Claims 1 - 10, 13 - 19, and 21 - 45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarov et al., United States Patent 6,110,204 ("Lazarov") in view of Shimada in Japanese patent application publication JP11-313884 ("Shimada").

Applicants respectfully traverse the Examiner's rejection for at least the following reasons.

Applicants assert that the Examiner has not established a prima facie case for obviousness under 35 U.S.C. 103(a). As noted in the recent Supreme Court case *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____, 82 USPQ 1385 (2007), the factual inquiries enunciated in *Graham v. John Deere Co.*, 383 US 1, 148 USPQ 459 (1966) form the basis for a determination of obviousness. These factors are:

- (1) Determining the scope and the content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art;
- (3) Resolving the level of ordinary skill in the pertinent art;
- (4) Secondary considerations.

Once the determination of the above factors has been made, then the determination of the obviousness or non-obviousness of the invention can be made.

With respect to the first prong, the Examiner states that Lazarov “discloses titanium-nitride-oxide (TiN_xO_y) compound disposed about a stent substrate substantially as claimed.” Regarding Shimada, the Examiner states that it “teaches a stent can have a coating material implanted at a depth within the surface of the stent (see figure 1) to reduce the probability of the coating from peeling off the stent.”

With respect to the second prong, the Examiner has pointed out one difference between the claimed invention and Lazarov when he states “Lazarov reference does not disclose the compound is implanted on a molecular or atomic level[1] at a depth in the surface of the stent.” The Examiner does not make any findings regarding the difference between the claimed invention and Shimada.

With respect to the third prong, the Examiner has made no findings.

Then the Examiner proceeds to his conclusion of obviousness based upon the combination of Lazarov and Shimada. The Examiner states that the motivation for the combination of Lazarov and Shimada is “to reduce the probability of the coating from peeling off the stent.”

As noted in the recently published “Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*,” Federal Register, 72(195), 57526, 57528-57529 (Wednesday, October 10, 2007/Notices) (“Post-KSR Examination Guidelines”):

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting

In re Kahn stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

Thus, as the Examiner has failed to make any findings with respect to the level of ordinary skill in the art, the Examiner has not established a prima facie case for obviousness.

Moreover, Applicants assert that the claimed invention is not obvious in light of the combination of Lazarov in view of Shimada. Applicants respectfully disagree with the Examiner’s conclusion that one of ordinary skill in the art would combine the references to obtain applicants’ claimed invention.

First, as stated by the Examiner, Lazarov does disclose a coating on the surface of an implant, and the coating material contains a compound of the formula MN_xO_y where M is a metal, preferably titanium, and with x and y taking values from 0.1 to 1.7 (column 2, lines 41- 47). However, Lazarov also specifies, in addition to the chemical composition recited above, 2-45% voids of the size $(0.4\text{ nm})^3$ to $(20\text{ nm})^3$ (column 4, lines 15 – 16). More specifically, the coating of Lazarov specifies a particular density range of 3.5 g/cm^3 to 5.4 g/cm^3 (column 3, line 11).

Furthermore, the porosity is critical to the invention of Lazarov as the reference states “[t]hese very voids result in the properties specific to the invention” (column 2, lines 35-36). Porosity is controlled by processing parameters as “it is necessary to adjust the production parameters such that the portion of voids is foreseeable” (column 4, lines 24-26).

Shimada teaches ion implantation of carbon in a substrate such as stent, and then a coating process based on plasma. Shimada specifies metals and metallic alloys as stent material which serves as the substrate for the coating of the invention. The key point of

the Shimada reference is a laminated layer formed by alternating between ion implantation and deposition. As noted in the translation of Shimada, paragraph 24, “[a]s described above, since the carbon ion implantation is alternated with the DLC film coating process and the layers are laminated, the adhesive strength of the DLC film is improved and the peeling resistance is increased.”

Applicants’ claimed invention differs from both references. Although applicants’ claimed invention includes the same chemical compound as cited in Lazarov, applicants’ invention differs in structure. First, applicants’ claimed invention includes the TiN_xO_y compound implanted at a depth within at least a region of the surface. There are no limitations on porosity in applicants’ invention. The coating of Lazarov, although including the TiN_xO_y compound, does not include implanted compound. Moreover, a key to the invention of Lazarov is the porosity of the layer.

Applicants’ claimed invention also differs from Shimada. The coating of Shimada includes implanted carbon (a “carbon implant layer”) and a diamond-like-carbon layer above the carbon implant layer. As noted above, the layers are laminated. Applicants’ claimed invention does not require laminated layers. Moreover, Shimada discloses the implantation of carbon ions. Applicants’ invention includes a TiN_xO_y compound below the surface, not carbon ions.

The level of ordinary skill in the art would be an engineer or scientist, such as a physicist, chemist, or materials scientist. In general, the person of ordinary skill in the art would be someone with a bachelors of science in engineering or science, and one who has worked with materials.

One of ordinary skill in the art would not combine the references to make applicants' claimed invention. As noted in the Post-KSR Examination Guidelines at page 57528 of the Federal Register Notice, "[a]scertaining the differences between the claimed invention and the prior art requires interpreting the claim language, and considering both the invention and the prior art as a whole." When Lazarov is viewed as a whole, the coating is a compound of a particular chemical formula and a specified porosity. To obtain the desired porosity, in particular, Lazarov notes that the coating is applied "by means of both the CVD and PVD method, but especially preferably by the PVD method" (column 4, lines 1-3). Furthermore, the porosity is controlled by processing parameters as "it is necessary to adjust the production parameters such that the portion of voids is foreseeable" (column 4, lines 24 - 26). The invention of Shimada is differentiated from conventional diamond-like carbon films manufactured by CVD (chemical vapor deposition) and PVD (physical vapor deposition) (Shimada, paragraphs 3 and 4).

Therefore, Lazarov teaches away from the use of the process of Shimada. "[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). Furthermore, as noted in MPEP 2145.X.D.2, "[i]t is improper to combine references where the references teach away from their combination." *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).

As outlined above, the porosity of the layer is key to the invention of Lazarov, and is controlled by careful selection and control of the processing parameter in the CVD or PVD process. In contrast, Shimada's invention involves using a different process than

the CVD or PVD process. Thus, one of ordinary skill in the art would not be lead to combine Lazarov with Shimada as Lazarov teaches the criticality of controlling the porosity through control of the CVD and PVD processing parameters.

Moreover, even if *arguendo*, one of ordinary skill in the art were to use the process of Shimada to apply the coating of Lazarov, applicants' claimed invention would not result. As noted above, Shimada teaches ion implantation of carbon in a substrate such as stent. Applicants' claimed invention includes the TiN_xO_y compound which is implanted at a depth within at least a region of the surface. Applicants' claimed invention is obtained by implantation of Titanium followed by a chemical reaction. Shimada does not disclose a chemical reaction step after ion implantation. Shimada discloses film coating after ion implantation, as well as alternating between the two processes.

Although, according to the Post-KSR Examination Guidelines, differences between the claimed invention and the prior art alone do not make the claimed invention non-obvious, the claimed invention is obvious only if the differences are not "so great." In this case, however, the differences are great enough to make the invention non-obvious. To obtain applicants' claimed invention, one would need to substitute the chemical reaction for the film coating after the ion implantation, forgo the alternation of the ion implantation and layering, and reject the porosity mandate of Lazarov. As the alternation of the two processes is one of the key steps for the increased adhesiveness, it would not be obvious to forgo the alternation of the two processes and expect to retain increased adhesiveness. Without an expectation of increased adhesiveness, the record is bare of any facts suggesting a motivation to combine Shimada and Lazarov. And for this reason, as well, *prima facie* obviousness is lacking on the record.

Moreover, as outlined above, application of the process of Shimada to the coating of Lazarov to obtain applicants' claimed invention would also require one to ignore the porosity limitations of Lazarov. The Examiner has not provided any justification on the record for ignoring this aspect of Lazarov, an aspect that Lazarov explicitly requires.

Thus, as the Examiner has not established a prima facie case for obviousness, applicants respectfully request the removal of the 35 U.S.C. 103(a) rejection of claims 1 - 10, 13 - 19, and 21 - 45.

4. With respect to the Examiners' comment that the combination would not impact the biocompatibility, applicants would like to point out that this does not cure the deficiency of the Examiner's prima facie case.

5. Regarding the Examiner's comments with respect to claims 7, 17, 24, and 40, even if the fact asserted by the Examiner is true, that is the assertion that stainless steel is abundant and easy to manufacture and use, this assertion does not cure the deficiency in the Examiner's prima facie case. The Examiner has merely provided a motivation for the choice of substrate, but not a motivation for the modification and surface coating of the present invention. Therefore, claims 7, 17, 24, and 40 are patentably allowable over the combination of Lazarov in view of Shimada. Applicants respectfully request the removal of the rejection of claims 7, 17, 24, and 40.

6. With respect to the Examiner's comments regarding claims 3, 6, 30, and 33, the Examiner's assertion, that "the thickness and depth of the coating or implanted layer is well-known in the art," even accepted as true, does not does not cure the deficiency in the Examiner's prima facie case. Thus, claims 3, 6, 30, and 33 are patentable over the combination of Lazarov in view of Shimada. Applicants respectfully request the removal of the rejection of claims 3, 6, 30, and 33.

7. With respect to claims 34, 42, and 44, the Examiner commented that the Shimada reference "teaches a carbon compound can be implanted into the stent substrate to increase the hardness of the coating, thereby increasing the wear resistance of the stent." Applicants respectfully assert that the Examiner has misinterpreted the Shimada reference. The Shimada reference states that the diamond-like carbon film has abrasion resistance, and does not attribute this property to the carbon-implanted layer onto which the diamond-like carbon layer is formed. Moreover, as outlined above, Lazarov teaches away from the combination of references, and therefore, claims 34, 42, and 44 are patentable over the combination of Lazarov in view of Shimada. Applicants respectfully request the removal of the rejection of claims 34, 42, and 44.

8. Claims 1 - 10, 13 - 19, 21 - 33, 35 - 41, 43 and 45 were rejected under 35 U.S.C. 103(a) as being unpatentable over Windecker et al., "Stent Coating With Titanium-Nitride-Oxide for Reduction of Neointimal Hyperplasia", ("Windecker") in view of Mora et al., United States Patent 6,632,470 ("Mora").

Applicants respectfully traverse the Examiner's rejection for at least the following reasons.

Applicants assert that the Examiner has not established a prima facie case for obviousness under 35 U.S.C. 103(a). As noted in the recent Supreme Court case *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____, 82 USPQ 1385 (2007), the factual inquiries enunciated in *Graham v. John Deere Co.*, 383 US 1, 148 USPQ 459 (1966) form the basis for a determination of obviousness. These factors are:

- (1) Determining the scope and the content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art;
- (3) Resolving the level of ordinary skill in the pertinent art;
- (4) Secondary considerations

As outlined above, the determination of obviousness or non-obvious occurs after these four factor have been evaluated.

Windecker discloses a stent with a TiN_xO_y coating. Mora discloses means of changing surface properties of a medical device.

As noted above, the level of ordinary skill in the art would be an engineer or scientist, such as a physicist, chemist, or materials scientist. In general, the person of ordinary skill in the art would be someone with a bachelors of science in engineering or science, and one who has worked with materials.

Applicants independent claims 1, 13, 19, 21, 23, 28, 34, 35, 43, and 44 include the word "implant." Applicants independent claims 9 and 26 include the feature of a compound "beneath" another layer such that it is "subsurface," or "blended with the surface material." Thus, all independent claims require some change to the material below a re-

gion of the surface of the stent. Neither Mora nor Windecker disclose ion implantation or modification of the region below the surface, either expressly or inherently. Therefore, the references do not teach all of the claim limitations.

As noted above, Windecker discloses a stent with a TiN_xO_y coating, and Mora discloses means of changing surface properties of a medical device. Neither Mora nor Windecker expressly discloses ion implantation. Windecker discloses coating the stent by “reactive physical vapor deposition in a vacuum chamber” (p. 929, “stent coating” section). With respect to metals, Mora discloses methods to obtain “desirable surface properties.”

There is also no inherent disclosure in either reference. Although a reference may not expressly disclose the property, the property may be inherent in the material or process disclosed. As MPEP 2112(V) states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. ... Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. ... In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Windecker only discloses “reactive physical vapor deposition.” This disclosure implies deposition of a film on the surface of the device. Although Mora discloses treatment of devices with a plasma at 13.56 Hz at 0 to 300 W power, and with a feed gas, the methods disclosed are described as “plasma treatment” or “plasma deposition.” Plasma deposition, as referred to in Mora, involves use of propylene as a feed gas and results in a film

deposited on top of the device. Plasma treatment in Mora involved air as a feed gas. For materials such as polymers, "air plasma treatment introduces oxygen containing functionalities on the surface" (column 8, lines 13 - 15). With respect to metal substrates, "[a]ir plasma treatment of metallic materials mostly exerts a cleaning effect, leading to the removal of hydrocarbon or, in general, organic contaminants, from the metal surface." Thus, the procedures as described involve only surface modification, and not sub-surface modification of the materials.

In sum, neither Mora nor Windecker disclose, either expressly or inherently, the feature of implantation, or modification, of a region below the surface. Despite the Post-KSR Examination Guidelines discussion that mere fact of differences alone do not make the invention non-obvious, in this case the differences are significant.

The Examiner states that the motivation for the combination of the two references is "to improve biocompatibility of the stent and to ensure that coating compound (TiN_xO_y) does not peel away from the stent." There is no disclosure of implantation below the surface in either of the two references. As the implantation below the surface would require different types of processing, this difference is significant. Furthermore, the Examiner has not explained why the differences would be obvious. As noted in the Post-KSR guidelines at page 57528, "Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art." The Examiner has provided no such explanation.

Thus, the Examiner has not established his prima facie case of obviousness. Applicants respectfully request the removal of the rejection under 35 U.S.C. 103(a) of claims 1 - 10, 13 - 19, 21 - 33, 35 - 41, 43, and 45.

Applicants respectfully submit that the pending claims are in condition for allowance. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. **07-1850**. If I can be of any help, please contact me at the number below.

Respectfully submitted,

Date:

November 6 2007

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0397
ggusler@ssd.com

Gloria M. Gusler

Gloria M. Gusler, Ph.D.
Attorney for Applicants
Reg. No. 50,282